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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,270	09/24/2003	Peter A. Altman	212/511	3869

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CROCKETT & CROCKETT  
24012 CALLE DE LA PLATA  
SUITE 400  
LAGUNA HILLS, CA 92653

EXAMINER

CHENG, JACQUELINE

ART UNIT PAPER NUMBER

3768

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/671,270	ALTMAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jacqueline Cheng	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 September 2003 and 05 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/9/04, 9/24/03</u>   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. **Claim 1-4, 6, 11-14, 16, 21-24, 26, 31-34, and 36** are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 5,637,113 (herein referred to as Tartaglia et al.). Tartaglia et al. discloses a stent wrapped with a polymer film capable of carrying and releasing therapeutic drugs. The stent can be implanted (which is an angioplasty procedure) in coronary arteries or any other part of the vasculature where mechanical opening force is necessary to keep the vessel open (col. 1 line 42-56). Depending on where the stent is implanted depends on where the therapeutic drug, such as an anti-inflammatory agent (which is an anti-restenosis agent, see col. 1 line 58-60 of US Patent No. 5,510,077), is injected. If the stent is placed near the endocardial or peri-adventitial area, the therapeutic agent will be injected from these areas.

3. **Claim 41** is rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 5,981,568 (herein referred to as Kunz et al.). Kunz et al. discloses a kit comprising a catheter for delivery of a therapeutic agent, at least one dosage unit of the therapeutic agent, as well as

instruction means for their use which is used for inhibiting stenosis or restenosis of a blood vessel (col. 10 line 63-col. 11 line 5).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 5, 7, 15, 17, 25, 27, 35, and 37** are rejected under 35 U.S.C. 103(a) as being unpatentable over Tartaglia et al. as applied to claim 1 above, and further in view of US Patent No. 6,152,141 (herein referred to as Stevens et al.). Stevens et al. discloses many agent delivery techniques such as injecting the agent directly into the myocardium by piercing the artery wall. This piercing is done distal to the stent site as can be seen in figure 10b (col. 8 line 37-49). Another agent delivery technique is to have a stent impregnated with a desired agent for a timed release to the surrounding vasculature (col. 9 line 40-43). It would be obvious to one with ordinary skill in the art at the time of the invention to combine Stevens et al. with Tartaglia et al. as both inventions are to stent placement with therapeutic agent delivery in the myocardium.

6. **Claims 8, 10, 18, 20, 28, 30, 38, and 40** are rejected under 35 U.S.C. 103(a) as being unpatentable over Tartaglia et al. as applied to claim 1 above, and further in view of US Patent No. 6,099,561 (herein referred to as Alt). Alt discloses a gene transfer agent, which can be used to prevent restenosis, that can be incorporated in a microsphere or liposome form (col. 6 line 38-

45). It would be obvious to one with ordinary skill in the art at the time of the invention to combine Alt with Tartaglia et al. as Tartaglia et al. discloses that any other therapeutic drugs may be used with the invention (col. 6 line 23-25).

7. **Claims 9, 19, 29, and 39** are rejected under 35 U.S.C. 103(a) as being unpatentable over Tartaglia et al. as applied to claim 1 above, and further in view of US Patent No. 5,443,495 (herein referred to as Buscemi et al.). Buscemi et al. discloses that highly active cross-linking agents, which prevent restenosis by hardening the stent, are encapsulated within micelles (col. 5 line 60-63). It would be obvious to one with ordinary skill in the art at the time of the invention to combine Buscemi et al. with Tartaglia et al. as both inventions are to stents and angioplasty procedures.

### ***Conclusion***


8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline Cheng whose telephone number is 571-272-5596. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3768

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JC

  
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